Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GORDON Y. K. NG, PHILIP SEEMAN, SUSAN R. GEORGE and BRIAN F. O'DOWD

Appeal No. 2001-2408
Application No. 08/670,119

ON BRIEF

Before, WILLIAM F. SMITH, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we vacate[1] the pending rejections and remand the application to the examiner to consider the following issues and to take appropriate action.

[1] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

Claim 18 is illustrative of the subject matter on appeal and is reproduced below:

18. A method of treating, in a mammal, a disorder for which administration of an antagonist of an integral membrane protein having at least one transmembrane domain is indicated, said method comprising administering to the mammal an effective amount of an antagonist peptide consisting essentially of at least four consecutive amino acid residues from the amino acid sequence of said at least one transmembrane domain or a conservative amino acid substitution variant of said peptide to specifically inhibit the activity of the integral membrane protein.

The references relied upon by the examiner are:

Murphy et al. (Murphy) 5,508,384 April 16, 1996

Rudinger, Characteristics of the amino acids as components of a peptide hormone sequence, in Peptide Hormones, pp. 1-7 (J.A. Parsons ed., University Park Press, Baltimore) (1976)

(Merk Manual), The Merck Manual of Diagnosis and Therapy, pp. 2657 (Robert Berkow ed., Merck Research Laboratories, Rathway, NJ) (1992)

Lofts et al. (Lofts), "Specific short transmembrane sequences can inhibit transformation by the mutant new growth factor receptor in vitro and in vivo," Oncogene, Vol. 8, pp. 2813-2820 (1993)

GROUNDS OF REJECTION

Claims 18, 20-37 and 60-65 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.

Claims 18, 20-37 and 60-65 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 18, 20-22, 36, 60 and 61 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lofts.

Claims 18, 20-22, 36, 60 and 61 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Murphy.

DISCUSSION

As set forth in In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998), "[t]he name of the game is the claim." In considering the issue of patentability "analysis begins with a key legal question – what is the invention claimed?" since "claim interpretation ... will normally control the remainder of the decisional process." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.).

In this regard, we note the claimed invention is drawn to a method of treating, in a mammal, comprising administering to the mammal an effective amount of an antagonist peptide. While the claim defines the antagonist peptide as consisting essentially of at least four consecutive amino acid residues from the amino acid sequence of at least one transmembrane domain or a conservative amino acid substitution variant of said peptide, it is not clear whether the claimed method is limited to the administration of a peptide drug. See e.g., Brief, page 8 (where appellants argue that Lofts, cited by the examiner as 102(b) prior art, did not "conceive of administering any portion of an integral membrane protein as a drug.").[2] Despite appellants' position, we note that the claim method does not appear to exclude the administration of an expression vector capable of expressing an effective amount of an antagonist peptide, and that page 16 of

[2] To illustrate our point we direct attention to the discussion of the Lofts reference in both the Answer and the Brief.

appellants' specification contemplates the application of gene therapy in the context of the claimed invention.

While appellants' assertion (Brief, page 8) that Lofts teach "transmembrane sequences had to be expressed within a cell," the examiner discusses the Lofts reference in terms of peptides. See e.g., Answer, page 17. Therefore, it does not appear that the examiner has considered whether the claimed invention may include within its scope the administration of an expression vector capable of expressing an antagonist peptide. In addition, we are unable to identify any portion of the Answer where the examiner has interpreted the claimed invention. Instead, we find the examiner's application of prior art based upon speculative assumptions as to what the claimed invention includes within its scope. See e.g., Answer, page 19 (wherein the examiner finds that the prior art "reasonably meet this ambiguous claim limitation of being 'at least four amino acids from ... at least one transmembrane domain.'").

For the forgoing reasons, we think it infelicitous to adjudicate the merits of the examiner's rejections where, as here, we must necessarily speculate with respect to the meaning of terms employed in the claims. Cf. In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962) (Examiner and Board were wrong in relying on what at best are speculative assumptions respecting the meaning of the claims and basing a rejection under 35 U.S.C. § 103 thereon). Rather, during patent prosecution when claims can be amended, ambiguity should be recognized, scope and breadth of language explored, and clarification

imposed. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Accordingly, we vacate the rejections of record and remand the application so that both appellants and the examiner may have the opportunity to cooperatively fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process. Zletz, 893 F.2d at 321, 13 USPQ2d at 1322. When it has been determined that the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity, we recommend that the examiner reevaluate the patentability of all of the appealed claims over the relevant prior art. If, on reflection, the examiner finds that a rejection is appropriate, the examiner should issue an appropriate Office action setting forth such rejection, using the proper legal standards and clearly setting forth the facts relied upon in support of such a rejection.

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

OTHER ISSUES

While we take no position on the merits of the rejection of record, we make the following observations in an effort to advance prosecution.

1. It is not a function of the claims to specifically exclude possible inoperative embodiments

We recognize the examiner's argument (Answer, page 6), "a disease state such as Parkinson's disease is characterized by dopamine receptor inactivity, versus over-activity, which contradicts the feasibility of the instant invention for 'treating ... disorders' generically, as 'indicated'." To the extent that the examiner is concerned that the claimed invention includes within its scope possible inoperable embodiments we note as set forth in Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances.... In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

2. To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph nothing more than objective enablement is required

We recognize the examiner's reference to page 2657 of the Merck Manual, emphasizing that Huntington's disease has no known origin or specific therapy.

Page 2657 of the Merck Manual, states in relevant part that Huntington's disease has "[n]o specific therapy." While the examiner is apparently relying on this statement to support his reasons for doubting the assertions in the specification, it is unclear how this statement relates to appellants claimed invention and supporting disclosure.

In this regard, we remind the examiner that in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

3. Indefinitness

We remind the examiner that the legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonable apprises those of skill in the art of its scope. See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). As set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

In this regard, we recognize appellants' argument (Brief, page 7) that the phrase "is indicated ... is not indefinite and that its ubiquitous usage in medical literature demonstrates that a person of ordinary skill in the art will readily understand its meaning." In responding to appellants' argument, the examiner simply restates his conclusion (Answer, page 15), "one reasonably cannot determine the metes and bounds of what is being 'indicated' without stating such." This conclusion, however, is not the type of fact-based reasoned analysis required to determine whether those skilled in the art would understand what is claimed. We remind the examiner that a claim is not necessarily indefinite simply because its scope is broad. If upon further prosecution, the examiner believes that the claims are

indefinite, the examiner should provide a reasoned fact-based analysis clearly explaining why a person of ordinary skill in the art would not understand what is claimed.

4. Does Lofts teach a gene therapy treatment of a disorder within the scope of the claimed invention.

We recognize the examiner's rejections under the first and second paragraphs of 35 U.S.C. § 112 include, inter alia, a question of "what the metes and bounds of the recitation 'treating ... a disorder' in a mammal entails" (see Answer, pages 4 and 8). In this regard, we note appellants' characterization of Lofts (Brief, page 8); Lofts "studied the effect of causing neu-transformed cancer cells to express within themselves portions of the neu oncogene. ... The growth of these transformed cells was studied in neu mice, allowing the affect of neu oncogene expression within the tumor cells on Tumor cell growth to be observed." In the event of further prosecution, the examiner should consider whether Lofts teach a the treatment of a disorder falling within the scope of the claimed invention.

5. Is Murphy enabled?

According to appellants (Brief, page 10), Murphy "does not teach or disclose a specific inhibition of dopamine D2 receptor activity, and certainly does not teach that peptides derived from a transmembrane domain of an integral membrane protein will act as antagonists of that protein." It appears that appellants are arguing that Murphy does not enable a method as set forth in appellants' claimed invention. In the event of further prosecution, the examiner

should consider whether Murphy provides an enabling disclosure of the subject matter relied upon by the examiner.

VACATED and REMANDED

William F. Smith)
Administrative Patent Judge)
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)
Donald E. Adams)
Administrative Patent Judge) BOARD OF PATENT
) APPEALS AND
)
Lora M. Green) INTERFERENCES
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